UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,992	01/22/2004	Maurice Cohen	5967.US.C1	8330

23492 7590 07/21/2005

ROBERT DEBERARDINE
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008

EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/763,992	COHEN ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *10-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☒ Claim(s) *1,3 and 6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/1/04*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *7/15/05*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to method of detecting nucleic acid, classified in class 435, subclass 6.

II. Claims 10-20, drawn to nucleic acids, host cells, kit comprising nucleic acid, gene, composition comprising nucleic acid, classified in class 536, subclass 23.1.

Note: Upon election of any ONE of the Groups above, applicant must further elect ONE sequence from SEQ ID NOS: 1-10, as each individual sequence is an independent group, not a species. Applicants are reminded that any claims not reading on the elected sequence will be withdrawn as being drawn to a non-elected invention.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as isolating a product that binds to the nucleic acid.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

2. During a telephone conversation with Lisa Mueller on 7/15/05 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-9 and invention SEQ ID NO: 9. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 1-9 are currently under prosecution.

Claim Objections

3. Claims 1, 3, and 6 are objected to for reciting "SEQ ID NOS 1-10" as said sequences are inclusive of non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth the PS112-specific polynucleotide or oligonucleotide wherein said polynucleotide or oligonucleotide comprises SEQ ID NO:9 and therefore the written description is not commensurate in scope with the claims drawn to a multitude of PS112-specific polynucleotides, complementary polynucleotides, or oligonucleotides with at least 50% identity to SEQ ID NO:9 and fragments and complements thereof.

The claims are drawn to a method of detecting the presence of a target PS112 polynulceotide or mRNA of PS112 in a sample comprising contacting the sample with a

PS112-specific polynucleotide, **complement thereof**, or PS112 oligonucleotide that has **at least 50% identity** to a polynucleotide consisting of SEQ ID NO:9 and **fragments or complements thereof**. The specification discloses SEQ ID No: 9 as PS112-specific polynucleotide or PS112 oligonucleotide. The specification defines a fragment of a specified polynucleotide as a polynucleotide sequence which comprises a contiguous sequence of approximately at least about 6 nucleotides, preferable at least about 8 nucleotides, more preferably at least about 10-12 nucleotides, and even more preferably at least about 15-20 nucleotides corresponding, i.e., identical or complementary to a region of the specified sequence (p. 12, lines 1-6). The specification does not disclose any other polynucleotides, polynucleotides complements, or oligonucleotides with 50% identity to SEQ ID NO: 9 and fragments or complements thereof as broadly encompassed in the claims.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a recitation of **"50% identity to, fragments of, or complements of SEQ ID NO: 9".** Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that " [a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name', of the claimed subject matter sufficient to distinguish it from other materials. " Id. At 1567, 43 USPQ2d at 1405. The court also stated that:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a

recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of polynucleotides, polynucleotide complements, or oligonucleotides with 50% identity to SEQ ID NO: 9 or fragments or complements of SEQ ID No: 9, per Lilly by structurally describing representative polynucleotides, oligonucleotides, fragments or complements or by describing "structural features common to the members of the genus, which

features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not directly describe PS112-specific polynucleotides, oligonucleotides, or complements thereof with 50% identity to SEQ ID NO: 9 and fragments or complements thereof as useful in the claimed invention in a manner that satisfies either the Lilly or Enzo standards. Although the specification discloses SEQ ID No: 9 and defines fragments of a polynucleotide as a contiguous sequence of at least 6 nucleotides to at least 20 nucleotides (wherein SEQ ID NO: 9 consists of 2,393 nucleotides which would comprise thousands of possible fragments or complements), this does not provide a description of the broadly claimed polynucleotides, oligonucleotides, or complements thereof with 50% identity to SEQ ID NO: 9 and fragments and complements thereof that would satisfy the standard set out in Enzo because the specification provides no functional characteristics coupled to structural features.

Further, the specification also fails to describe PS112-specific polynucleotides, complements, or oligonucleotides, with 50% identity to SEQ ID NO: 9 and fragments and complements thereof by the test set out in Lilly because the specification describes only SEQ ID NO: 9. Therefore it necessarily fails to describe a representative number of such species.

Thus, the specification does not provide an adequate written description of PS112-specific polynucleotides, complementary polynucleotides, and oligonucleotides with at least 50% identity to SEQ ID NO: 9 and fragments and complements thereof that is required to practice the claimed invention. Since the specification fails to adequately describe the product to which the claimed method of detecting the presence of PS112 polynucleotide uses, it also fails to adequately describe the method.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,110,675. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the US Patent and instant application are drawn to the methods of detecting the presence of PS112 polynucleotide and mRNA of PS112 in a test sample.

Claims 1-9 of the instant application correspond to claims 1-9 of the US Patent. Claims 1 and 2 of the US Patent and instant application are drawn to a method of detecting PS112 polynucleotide in a sample comprising contacting the sample with PS112-specific polynucleotide SEQ ID NO: 9 wherein the PS112 polynucleotide is attached to a solid phase. Claims 3-5 of the US Patent and instant application are drawn to a method of detecting mRNA of PS112 in a sample. Claims 6-9 of the US Patent and instant application are drawn to a method of detecting PS112 polynucleotide in a sample comprising contacting the sample with a PS112 oligonucleotide as a sense and anti-sense primer to amplify a first stage reaction product, contacting the first stage reaction product with another PS112 oligonucleotide to obtain a second stage reaction product, and detecting the second stage reaction product as an indication of the presence of the PS112 polynucleotide, wherein the test sample is reacted with a solid phase, wherein the detection step comprises utilizing a detection label capable of generating a measurable signal, wherein the detectable label is reacted to a solid phase.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER